

### **REMARKS**

Claims 9 and 23 are amended herein solely to correct form. Claims 22 and 28-43 are canceled herein, without prejudice as to pursuit of protection of the subject matter of these claims in a related application. New claims 44-47 are added herein. Support for new claims 44-47 can be found throughout the specification, for example on page 2, lines 29-31, page 6, line 36, page 8, lines 29-35, page 9, lines 7-12 and lines 28-34, page 11, line 32 to page 12, line 15, and on page 14, lines 2-4. After entry of this amendment, claims 9, 11, 12, 14, 16, 23-27, and 44-47 are pending in the application.

No new matter has been added. Reconsideration of the subject application is respectfully requested.

### **Telephone Interview**

Applicants thank Examiner Whiteman for the helpful telephone interview on January 5, 2005, wherein support for claims 16, 27-43 and new claim 44 was discussed.

### **Election/Restrictions**

Claims 11, 24, 32, and 40 are objected to for being drawn to non-elected subject matter. Claims 32 and 40 are canceled herein, rendering the objection moot as applied to claims 32 and 40.

Applicants note that an election of species (with traverse) was made on June 25, 2002. This response specifically pointed to errors in the requirement for the election of species. In addition, the Office action dated October 3, 2002, stated that the species not elected from claims 3, 11, and 18 were withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to a non-elected species.

Applicants further note that upon allowance of a generic claim, they are entitled to consideration of claims to additional species that are written in dependent form. MPEP 809.02 states that when a generic claim is rejected, claims readable on the non-elected species should be considered to be withdrawn. When the generic claim is subsequently found to be allowable, the claims drawn to the non-elected species are no longer considered to be withdrawn (see MPEP

809.02(B)(1)). As such, Applicants respectfully submit that cancellation or amendment of claims 11 and 24 is not required at this time. This subject matter should be considered to be withdrawn at this time. Applicants reserve the right to petition the requirement for an election of species.

### **Claim Objections**

Claim 9 is objected to because the term “a” on line two before the words “nucleic acid” was allegedly removed inappropriately. Claim 9 is amended herein to correct form and now recites “a” before the words “nucleic acid” on line 2. Reconsideration and withdrawal of this objection is respectfully requested.

### **Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 28-43 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully disagree with this rejection. However, to advance prosecution in this case, Applicants have canceled claims 28-43 herein, rendering this rejection moot.

Claim 22 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully disagree with this rejection. However, to advance prosecution in this case, Applicants have canceled claim 22 herein, rendering this rejection moot.

Claims 16, 27, 35, and 43 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office action asserts that there is no written description of a method for the treatment of diabetic ischemic disease in a subject, comprising administering a nucleic acid encoding HGF once every few weeks or once every few days, wherein at least 50  $\mu$ g of the nucleic acid is administered to the subject. Applicants respectfully disagree with this rejection. However, as discussed above, Applicants have canceled claims 35 and 43 herein, rendering this rejection moot as applied to claims 35 and 43.

As was discussed in the telephone interview with Examiner Whiteman on January 5, 2005, support for administering a nucleic acid encoding HGF (*i.e.*, the “therapeutic agent”) once every few weeks or once every few days, wherein at least 50  $\mu$ g of the nucleic acid is administered to the subject is found on page 9, lines 28-33:

“Dosage of the **therapeutic agent** of this invention varies depending on the symptoms of the patient but HGF genes about 1  $\mu$ g to about 50 mg, preferably about 10  $\mu$ g to about 5 mg, more preferably about 50  $\mu$ g to about 5 mg per adult patients can be defined.

The **therapeutic agent** of this invention is suited for administration once every few days or once every few weeks.” [emphasis added]

Thus, on page 9, lines 28-31, support for administering at least 50  $\mu$ g of a nucleic acid encoding HGF (*i.e.*, the “therapeutic agent”) is clearly found. Likewise, in lines 32-33 of the next paragraph clear support for administration of the therapeutic agent of the invention (*i.e.*, a nucleic acid encoding HGF) once every few days or once every few weeks is found. Therefore, Applicants submit that the specification does lead a person skilled in the art to administering a nucleic acid encoding HGF (at least 50  $\mu$ g) to a subject once every few weeks or once every few days. Reconsideration and withdrawal of the rejection, as applied to pending claims 16 and 27, is respectfully requested.

#### **Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 32, 33, 40, and 41 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter of the invention. Applicants respectfully disagree with this rejection. However, to advance prosecution in this case, Applicants have canceled claims 32, 33, 40, and 41 herein, rendering this rejection moot.

#### **Claim Rejections Under 35 U.S.C. § 102**

Claims 9, 11, 12, 14, 23-26, 28-34, and 36-42 were rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative obvious under 35 U.S.C. § 103(a), over U.S. Patent No.

6,248,722 (hereinafter the '722 patent), in view of the Gene Therapy of Osaka University, English translation from the Japan Financial News Paper, Local News Section (December 14, 1998). Applicants respectfully disagree with these rejections.

Applicants submit that the Declaration of Ryuichi Morishita and Toshio Ogihara, submitted herewith, overcomes these rejections. Specifically, Ryuichi Morishita and Toshio Ogihara are two of the co-inventors of the '722 patent. They are also named co-inventors of the present application. The Declaration states that any disclosure in the '722 patent relating to a method for the treatment of diabetic ischemic disease in a subject using hepatocyte growth factor gene therapy is solely the work of the inventors of the present application, namely Ryuichi Morishita and Toshio Ogihara. Thus, to the extent that the '722 patent discloses a method for the treatment of diabetic ischemic disease in a subject, that subject matter is the work of Ryuichi Morishita and Toshio Ogihara and not that "of another." In view of this Declaration, reconsideration and withdrawal of these rejections is respectfully requested.

### **Double Patenting**

Claims 9, 14, 23, 26, 28, 29, 30, 31, 34, 36-39, and 42 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 36 of co-pending Application No. 09/857,719 (hereinafter the '719 application), in view of the Gene Therapy of Osaka University, English translation from the Japan Financial News Paper, Local News Section (December 14, 1998). Applicants note that in an amendment to the '719 application dated January 24, 2005, claim 36 was canceled, rendering this provisional rejection moot.

### **Allowable Subject Matter**

Applicants thank Examiner Whiteman for indicating in the telephone interview held on January 5, 2005 that claim 16 would be allowable if written in independent form. Accordingly, new claim 44 is added herein, which is claim 16 written in independent form.

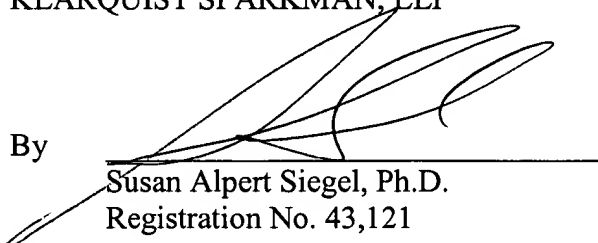
### Conclusion

Applicants submit that the pending claims are in condition for allowance, which action is requested. If any matters remain to be discussed before a Notice of Allowance is issued, Examiner Whiteman is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By



Susan Alpert Siegel, Ph.D.  
Registration No. 43,121

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 595-5300  
Facsimile: (503) 228-9446